

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS***DRUGS FOR HUMAN USE**

2330. Misbranding of Radium Ore, Colwell's Penetrating Healing Balm, and Radium Bath Powder. U. S. v. Carry Grace Colwell (Colwell Radium Company). Plea of not guilty. Tried to the jury. Verdict of guilty. Fine, \$500, and probation for 2 years. (F. D. C. No. 21481. Sample Nos. 53096-H, 59069-H to 59071-H, incl.)

INFORMATION FILED: July 23, 1947, District of Minnesota, against Carry Grace Colwell, also known as Mrs. J. H. Colwell, trading as the Colwell Radium Company, St. Paul, Minn.

ALLEGED SHIPMENT: From the State of Minnesota into the States of Ohio and Montana. The products were shipped on or about August 29 and September 20, 1946, and were accompanied by letters addressed to the consignees and by circulars entitled "Colwell Radium Co. Manufacturers of the World's Greatest Healing Remedies."

PRODUCT: Analyses showed that the *Radium Ore* consisted of a yellow and gray rock resembling carnotite, with a radium concentration in one portion of 30 parts per billion, and in another portion of 50 parts per billion; that the *Colwell's Penetrating Healing Balm* was a yellow ointment consisting essentially of glycerin, water, and paraffin, small amounts of borax and perfume, and a negligible radium content; and that the *Radium Bath Powder* was a mixture of magnesium sulfate and sodium sulfate, with small amounts of borax, carnotite, and perfume, and a radium concentration of 1 part per billion.

NATURE OF CHARGE: *Radium Ore.* Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented and suggested that the article would have a cleansing effect; that it would be helpful to most every ailment of the human body; that it would be a potent treatment for many stomach and intestinal disorders; that it would produce cell action and assist the organs of the body; that it would be efficacious in the cure, mitigation, and treatment of serious gland trouble; that it would build glands; that it was one of the world's greatest healing remedies; that it would be efficacious in the removal of cancer tumors; and that it would be efficacious in the cure, mitigation, and treatment of poliomyelitis (infantile paralysis), prostatic obstruction, gout, rheumatism, lumbago, sciatica, arthritis, neuritis, neuralgia, Bright's disease, liver disorders, high blood pressure, eczema, psoriasis, chronic skin disorders, obesity, chronic diarrhea, gastrointestinal disorders, fermentation, gastric dyspepsia, heart trouble, tonsil trouble, sinus trouble, hay fever, gall bladder trouble, kidney trouble, appendicitis, anemia, impotency, premature old age, paralysis, nervousness, gastric ulcers, nephritis, insomnia, flatulence, goiter, constipation, locomotor ataxia, diabetes, tuberculosis, asthma, bronchial trouble, tumors, and bone infection. The article would not have a cleansing effect; it would not be a potent treatment for many stomach and intestinal disorders; it would not produce cell action and assist the organs of the body; it was not one of the world's greatest healing remedies; it would not build glands; and it would not be efficacious for the other purposes represented.

Colwell's Penetrating Healing Balm. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented and suggested that the article was a penetrating healing balm; that it would be efficacious in the cure, mitigation, and treatment of sore muscles, aches, and pains; that it would build tissue, relax the nerves, and relieve sinus colds, skin infection, arthritis, neuritis, sciatica, rheumatism, swelling and inflammatory conditions, sinus, heart, and lung troubles, chronic appendicitis, menses, varicose veins, and similar ailments; and that it would be efficacious in the cure, mitigation, and treatment of serious gland trouble, and would build the glands. The article was not a penetrating healing balm, and it would not be efficacious for the purposes represented.

Radium Bath Powder. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading, since they represented

*See also Nos. 2301-2308, 2310, 2311, 2316, 2317, 2319-2329.

and suggested that the article would build the glands and that it would be efficacious in the cure, mitigation, and treatment of serious gland trouble, inflammatory and sciatic conditions, neuritis, lumbago, gout, arthritis and other forms of rheumatism, low vitality, cancer, tumors, appendicitis, diabetes, la grippe, high blood pressure, varicose veins, eczema, syphilis, erysipelas, scarlet fever, smallpox, prostatic obstruction, poliomyelitis, and alcoholic and cigarette poisoning. The article would not build glands, and it would not be efficacious for the purposes represented. Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, and distributor; and, Section 502 (b) (2), it failed to bear a label containing an accurate statement of the quantity of the contents, since it bore no label containing a statement of the quantity of the contents.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before a jury on November 21, 1947. The jury returned a verdict of guilty on December 1, 1947; on December 16, 1947, the court imposed a fine of \$250 on each of counts 1 and 2, suspended the imposition of sentence on counts 3 and 4, and placed the defendant on probation for a period of two years, conditioned that she bring the labeling of her products into compliance with the law.

2331. Misbranding of Fernel Intestinal Normalizer, Vitalgen, Fernel Slenda Creme, Fernel Obesine No. 1, Endogene, Slimming T-Ade, Climacteric No. 149, Roxor, Goat's Milk Capsules, Calcium Carduus Compound, Nedra, Linol, Neo-Serum Solution of Organic Marine Substances, Prostate Suppository, and Saw Palmetto & Silica Co. U. S. v. Dr. Jean Paul Fernel. Plea of not guilty. Tried to the jury. Verdict of guilty. Defendant sentenced to 1 year's imprisonment on each of 21 counts, with the sentence on counts 1, 2, and 3 running consecutively, the sentence on the remainder of the counts running concurrently with count 3, and the sentence on count 1 running concurrently with the sentence in a previous case. (F. D. C. No. 12547. Sample Nos. 15028-F to 15034-F, incl., 15037-F to 15039-F, incl., 49061-F, 49062-F, 49068-F, 52045-F, 54825-F, 57840-F, 59563-F, 59571-F, 60323-F, 67410-F, 72020-F.)

INFORMATION FILED: August 21, 1944, Northern District of Illinois, against Dr. Jean Paul Fernel, Chicago, Ill.

ALLEGED SHIPMENT: Between the approximate dates of December 31, 1943, and February 23, 1944, from the State of Illinois into the States of California, Indiana, Massachusetts, Wisconsin, Colorado, Maryland, Michigan, Ohio, and Missouri.

PRODUCT: Analyses disclosed that the *Fernel Intestinal Normalizer* consisted of capsules containing agar, Irish moss, bile extract, and nucleic acid-containing material such as duodenal extract; that the *Vitalgen* consisted essentially of magnesium chloride; that the *Fernel Slenda Creme* consisted essentially of ammonium carbonate, gum, and water, and perfumed and colored with a red dye; that the *Climacteric No. 149* consisted of tablets containing plant material and alkaloids, including strychnine, berberine, aconitine, hydrastine, and milk sugar; that the *Roxor* consisted of capsules containing essentially glandular material, dulse, zinc phosphide, and talc; that the *Goat's Milk Capsules* consisted essentially of milk sugar, fat, protein, a small proportion of a calcium compound, and water; that the *Fernel Obesine No. 1* consisted of capsules containing plant material, including dulse, bladder-wrack, and glandular material; that the *Endogene* consisted of capsules containing glandular material and plant material, including dulse; that the *Slimming T-Ade* consisted essentially of sassafras bark and orange peel; that the *Prostate Suppository* consisted essentially of ichthammol, benzocaine, and plant material, including belladonna and Hyoscyamus incorporated in a fatty acid base; that the *Saw Palmetto & Silica Co.* consisted of tablets containing plant material, milk sugar, and minute quantities of calcium sulfate and calcium fluoride; that the *Calcium Carduus Compound* consisted of tablets containing calcium sulfide, milk sugar, and small amounts of extracts of plant drugs; that the *Nedra* consisted of capsules containing glandular material, plant material, a small proportion of zinc phosphide, and talc; that the *Linol* consisted of linseed oil; and that the *Neo-Serum Solution of Organic Marine Substances* consisted essentially of water containing small proportions of organically combined iodine and sulfur, sodium iodide, and sodium chloride.